

**UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF NEW YORK**

IN RE HAIN CELESTIAL HEAVY
METALS BABY FOOD LITIGATION

Case No. 2:21-cv-00678-NM-AYS

**PLAINTIFFS' OPPOSITION TO
DEFENDANT'S MOTION TO DISMISS THE
CONSOLIDATED AMENDED CLASS ACTION COMPLAINT**

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Plaintiffs Asyia Andrews, Lisa Gans, Shahalis Wilson, Myjorie Philippe, Zeynep Senturk Mannix, Monica Hazelwood, Carolyn Leary, Bethany Nickerson, Lizette Romero Ortiz, Elena Thormahlen, Amanda Roman, Cassie Caldwell, Simone Craig, Cassie Isza, Helen Howard, Jade Huguenot, Stephanie Weimer, Jessie McNaughton, and Tanya Motsay (collectively, “Plaintiffs”) respectfully submit this memorandum of law in opposition¹ to Defendant Hain Celestial Inc.’s (“Defendant” or “Hain”) Motion to Dismiss Plaintiffs’ Consolidated Amended Class Action Complaint (the “Complaint” cited as “Compl. ¶ _”), ECF No. 160.²

I. INTRODUCTION

It is undisputed that baby foods directly impact the health and development of infants – one of society’s most vulnerable groups. For these reasons, parents rely on the labels of baby food products in order to select safe and healthy products for their babies’ consumption.

For decades, Hain represented that Earth’s Best Baby Foods³ were of particular quality, grade or standard and contained certain characteristics that the products do not actually possess. Compl. ¶ 101. Hain’s labels for Earth’s Best Baby Foods guarantee that, among other things, the products are “Grown without Potentially Harmful Pesticides or Herbicides,” contain “No Genetically Engineered Ingredients,” are “Organic,” “Pure” and made with “pure, quality products.” Compl. ¶¶ 4, 103-104.

Unbeknownst to purchasers, and contrary to Hain’s labels, Earth’s Best Baby Foods contain elevated levels of dangerous heavy metals and other toxins, including lead, arsenic, inorganic arsenic, cadmium, mercury, and perchlorate (collectively, “Dangerous Toxins”). Compl. ¶¶ 71, 73-74, 76, 78, 79. Purchasers were alerted of the Dangerous Toxins for the first

¹ To the extent Defendant raises new arguments in its reply, Plaintiffs respectfully request an opportunity to respond in a sur-reply.

² Internal quotations are omitted throughout.

³ Earth’s Best Baby Foods refers to the products sold under Defendant Hain’s Earth’s Best brand. *See* ECF No. 160, Ex. A.

time on February 4, 2021, when the Congressional Subcommittee on Economic and Consumer Policy (the “Congressional Subcommittee”) issued its report: *Baby Foods Are Tainted with Dangerous Levels of Arsenic, Lead, Cadmium, and Mercury* (the “Congressional Report”).

Compl. n.3. Hain, however, knew its products contained elevated levels of Dangerous Toxins – as evidenced by Hain’s implementation of internal testing standards with which, as it turns out, Hain failed to comply. Compl. ¶¶ 91-93.

Defendant Hain raises three arguments as purported grounds for dismissal: (i) that Plaintiffs have not alleged sufficient injury-in-fact to establish Article III standing; (ii) that Plaintiffs do not plausibly allege that Hain’s labeling is misleading; and (iii) that the primary jurisdiction doctrine applies to dismiss or stay this action. Contrary to Defendant’s arguments, Plaintiffs plead facts sufficient to defeat these three arguments.

First, Plaintiffs sufficiently demonstrate Article III standing and standing for injunctive relief. This is a false advertising case. To establish standing, Plaintiffs must demonstrate: (1) an injury-in-fact; (2) “a causal connection between the injury and the conduct at issue; and (3) the injury must be likely to be redressed by a favorable decision.” *Nicosia v. Amazon.com, Inc.*, 834 F.3d 220, 239 (2d Cir. 2016). Here, Plaintiffs adequately allege economic injury rooted in a benefit of the bargain or price premium theory. Assuming arguendo Plaintiffs are required to demonstrate risk of future harm to establish standing for injunctive relief, Plaintiffs have done so by alleging continued purchase and use of the products.

Second, Plaintiffs’ well-pled complaint sufficiently establishes Plaintiffs’ consumer protection act and deceptive practices claims. Plaintiffs demonstrate that they were materially misled by Hain’s label disclosures and omissions. Any argument to the contrary stems from a question of fact that cannot be resolved on a motion to dismiss. Moreover, the terminology Hain used on its labels, e.g., “Grown without Potentially Harmful Pesticides or Herbicides,” “No

Genetically Engineered Ingredients,” “Organic,” and “Pure,” are tied to clear, unequivocal definitions, the meaning of which may be assessed as a matter of law. *See* Compl. ¶ 103.

Third, the primary jurisdiction doctrine is not applicable here. Courts assess four factors in determining whether the doctrine applies. The factors are: (i) if the issue “is within the conventional experience of judges” or if “it involves technical or policy considerations within the [FDA’s] particular field of expertise;” (ii) “whether the question at issue is particularly within the [FDA’s] discretion;” (iii) “whether there [is] a substantial danger of inconsistent rulings;” and (iv) “whether a prior application to the agency has been made.” *Goldemberg v. J&J Consumer Cos., Inc.*, 8 F. Supp. 3d 467, 476 (S.D.N.Y. 2014). Here, all four factors weigh against staying or dismissing this case in favor of FDA action. Plaintiffs are not asking this Court to determine appropriate levels of Dangerous Toxins in baby foods. Instead, the issue here is whether consumers were misled by Hain’s labels and advertisements – an issue routinely handled by Courts. Further, there is no danger of inconsistent rulings because the FDA has not initiated action regarding baby food labeling and neither party has made such an application. It is well-settled that the issues in this action are squarely within the Court’s expertise and may be resolved without guidance or involvement from the FDA.

For these reasons, the Defendant’s Motion to Dismiss must be denied in its entirety.

II. STATEMENT OF FACTS

In 2021, the Congressional Subcommittee conducted testing on baby food products, including Earth’s Best Baby Food products manufactured by Defendant Hain, and published a report revealing the presence of elevated levels of Dangerous Toxins. Compl. ¶ 13. The news revealing that Hain’s Earth’s Best Baby Food affirmatively contained elevated levels of Dangerous Toxins came as a shock to Plaintiffs and consumers who had made the decision to

purchase Earth's Best Baby Food under the guise that it was superior to competing products. Compl. ¶¶ 15-18; 23-42.

Prior to Hain being exposed for having Dangerous Toxins in its baby food, Plaintiffs elected to purchase Earth's Best Baby Food products based on Defendant Hain's marketing and labeling for the products. Hain touted its products as: "Earth's Best," "pure," "pure quality products" "organic," made with "no genetically engineered ingredients," "babies' perfect first solid food," "whole grain natural goodness," "grown without potentially harmful pesticides or herbicides," and "easily digestible." Compl. ¶¶ 102-104. Given these representations, reasonable consumers believed Earth's Best Baby Foods were free of Dangerous Toxins, "pure," and made with "quality products" as advertised. Consumers trusted Hain to provide safe products for infants and never expected Hain to omit the serious and material fact that its infant products contained such high levels of Dangerous Toxins. Compl. ¶ 3.

Consumers' reaction in light of this revelation should not have come as a shock to Hain. Prior to the publication of the Congressional Report, Hain understood the concern associated with Dangerous Toxins in Earth's Best Baby Foods as evidenced by its implementation of internal guidelines to set acceptable levels of Dangerous Toxins. Defendant was also aware – unbeknownst to consumers – that it was using ingredients that exceeded the acceptable levels it established. Worse, while reasonable consumers would expect Defendant Hain to test its *finished* products, unbeknownst to Plaintiffs and consumers, Hain only tested *ingredients*. In short, Hain's testing revealed that the ingredients Hain used exceeded its own internal standards for Dangerous Toxins, yet Hain continued to put them in their products and sold them anyway. Defendant Hain could have taken reasonable steps to remove Dangerous Toxins from its products, but chose not to. Meanwhile, consumers were left in the dark, continuing to purchase

Defendant Hain's Earth's Best products and feeding them to their infants. Thus, exposing their babies to Dangerous Toxins on a daily basis for months, and even years when Plaintiffs believed they were purchasing a premium product that was "pure" and made with "pure quality ingredients."

Plaintiffs would not have paid Defendant Hain's premium prices for Earth's Best products had they known the truth about the products; Earth's Best Baby Foods were not "pure" and were not made with "quality products" as these products failed Hain's internal testing and were sold containing Dangerous Toxins. Plaintiffs unknowingly paid these prices for products they believed to be the "best" for their children, but had they known the truth, Plaintiffs would have and could have purchased alternatives that were less expensive and/or contained lower levels of Dangerous Toxins.

A. Summary of Related Cases

False advertising cases regarding food products are frequently heard and upheld in the Second Circuit. However, Hain continues to compare this action to other non-precedential cases. Accordingly, Plaintiffs summarize these out-of-circuit cases below. This action is not the first of its kind and would not be the first to survive a motion to dismiss. Both *In re Plum Baby Food Litigation* and *Kochar*, pled similar deceptive practices violations for the same underlying conduct of intentionally omitting the presence of Dangerous Toxins from their labels and both survived the motion to dismiss. *See In re Plum Baby Food Litig.*, 2022 WL 16640802 (N.D. Cal. Jan. 12, 2022); *Kochar v. Walmart, Inc.*, 21-cv-02343-JD, ECF No. 43 (N.D. Cal. Apr. 25, 2022). Defendant Hain attempts to downplay the similarities between *In re Plum Baby Food Litigation* and this case (MTD at n.8); however, the claims are practically identical. Any concern about the decision being out of circuit is alleviated by the fact that the precedential case law

governing the requisite standards and proof is overwhelmingly similar in the Second and Ninth Circuits.

Defendant's cited cases *Kimca*, *Gerber*, and *Plum/Campbell* are inapposite. *See Kimca v. Sprout Foods, Inc.*, (“*Kimca I*”), 2022 WL 1213488 (D.N.J. Apr. 25, 2022); *In re Gerber Prods. Co. Heavy Metals Baby Food Litig.*, 2022 WL 10197651 (E.D. Va. Oct. 17, 2022); *In re Plum Baby Food Litig.*, 2022 WL 16552786 (D.N.J. Oct. 31, 2022) (hereinafter “*Plum/Campbell*”). The Courts in *Kimca*, *Gerber*, and *Plum/Campbell* granted the motions to dismiss based on a standard that does not exist here – the need to demonstrate physical injury in order to establish Article III standing. The Court in *Plum/Campbell* further analyzed Plaintiffs’ purported failure to plead a risk of future harm. However, in this action, physical injury was specifically excluded so that this case could focus solely on mislabeling and false and deceptive advertising. *See* Consolidation Order, ECF No. 47 at 4 (“Hain objects to consolidation of actions asserting product liability claims or personal injury claims”). Thus, Hain defined the parameters of this case to exclude physical injury. *See id.*; Defendant’s Motion to Dismiss (“Motion to Dismiss” cited as “MTD at _”), at 13-16. Further, some Plaintiffs continue to purchase Earth’s Best Baby Food, even if in a lesser quantity, thereby facing a future risk of harm. Compl. ¶¶ 24, 33.

III. ARGUMENT

A. Plaintiffs sufficiently demonstrate Article III standing.

Plaintiffs have Article III standing because they suffered an economic injury that could have been avoided through truthful advertising and honest labeling, and this injury can be redressed by a favorable decision of this Court or jury. The standard requires that “(1) the plaintiff must have suffered an injury-in-fact; (2) there must be a causal connection between the injury and the conduct at issue; and (3) the injury must be likely to be redressed by a favorable decision.” *Nicosia*, 834 F.3d at 239. Hain correctly recited the legal standard but misapplied the

law in their analysis of Article III standing. MTD at 13-21. The Second Circuit has “repeatedly described [the injury-in-fact] requirement as a low threshold.” *John v. Whole Foods Mkt. Grp., Inc.*, 858 F.3d 732, 737 (2d Cir. 2017) (finding plaintiff “plausibly alleged a nontrivial economic injury sufficient to support standing: according to the DCA’s investigation, Whole Foods packages of cheese and cupcakes were systematically and routinely mislabeled and overpriced”). Plaintiffs meet, and surpass, this low bar by alleging that Earth’s Best Baby Foods contain Dangerous Toxins, based on the testing data included in the Congressional Report, and that the marketing for and labels on Hain’s products do not disclose it; instead, the marketing and labels advertise the foods, among other things, “pure” and made with “pure quality products.” Compl. ¶ 13; see *Lujan v. Defs. of Wildlife*, 504 U.S. 555, 561 (1992) (“At the pleading stage, general factual allegations of injury resulting from the defendant’s conduct may suffice”).⁴ Plaintiffs exceed the minimum standard by demonstrating cognizable economic injury under both a price premium and benefit of the bargain theory. See *Hughes v. Ester C Co.*, 930 F. Supp. 2d 439, 453 (E.D.N.Y. 2013) (collecting cases) (economic injury-in-fact is a well-settled “form of injury-in-fact that meets the first element of standing.”) Courts routinely find allegations of economic injury sufficient to confer Article III standing. “A plaintiff’s allegation that she purchased products bearing misleading labels and sustained financial injury as a result is sufficient to give that plaintiff Article III standing.” *Axon v. Citrus World, Inc.*, 354 F. Supp. 3d 170, 177 (E.D.N.Y. 2018), *aff’d sub nom. Axon v. Florida’s Nat. Growers, Inc.*, 813 F. App’x 701 (2d Cir. 2020); see also *In re Frito-Lay N. Am., Inc. All Nat. Litig.*, 2013 WL 4647512, at *11

⁴ Plaintiffs are not required to test their own baby food products in order to survive a motion to dismiss. See *John*, 858 F.3d at 736–37 (finding testing from government report about the Whole Foods products at issue “sufficient to defeat a motion to dismiss based on lack of injury where the plaintiff also alleged he bought pre-packaged products at Whole Foods”). Defendant’s own cited case, *Kimca I*, agrees, holding “plaintiffs can establish standing using representative testing where they allege that all of the products sold by the defendant contain the alleged defect.” *Kimca I*, 2022 WL 1213488 at *4.

(E.D.N.Y. Aug. 29, 2013); *Colpitts v. Blue Diamond Growers*, 527 F. Supp. 3d 562, 575 (S.D.N.Y. 2021) (“Such an allegation that a plaintiff would not have purchased a product or would not have paid the same amount comfortably satisfies the injury-in-fact prong of Article III standing.”). Hence, Hain’s flawed arguments that Plaintiffs cannot establish theories of economic injury or that a physical injury is required fail.

1. Hain’s misrepresentations and omissions induced Plaintiffs to pay inflated prices.

Economic injury-in-fact is demonstrated if Plaintiffs allege, as they have here, that they would not have purchased the product or would have paid less for it had they known the truth. “[T]he law is clear that economic injury—including that caused by paying a premium—is sufficient to establish injury for standing purposes.” *Kacocha v. Nestle Purina Petcare Co.*, 2016 WL 4367991 at *8 (S.D.N.Y. Aug. 12, 2016).

Under this theory, Plaintiffs must – and do – demonstrate plausible⁵ “[a]llegations that a plaintiff would not have bought the product or paid less for it had she known the truth behind the misrepresentation.” *Brown v. Kerry Inc.*, 2021 WL 5446007, at *3 (S.D.N.Y. Nov. 22, 2021); *Belcastro v. Burberry Ltd.*, 2017 WL 5991782, at *4 (S.D.N.Y. Dec. 1, 2017) (“A price premium injury may be alleged by showing either that because of a misrepresentation the plaintiff received a good worth less than what he paid for, *i.e.*, a good of inferior quality, or that because of a misrepresentation the plaintiff paid an inflated price.”). According to the Court, “the classic example” of price premium injury “is paying for fat free milk but receiving milk containing fat instead . . . or paying for dog food made from bacon that in fact contains grain fillers.” *Id* at 5. This is precisely what the Complaint alleges – paying for safe nutritious baby foods that in fact

⁵ To meet the “plausible” standard, a plaintiff need only plead “factual content that allows the court to draw the reasonable inference” asserted. *Gibson v. Bartlett Dairy, Inc.*, 2022 WL 784746, at *5 (E.D.N.Y. Mar. 15, 2022).

contain Dangerous Toxins. For example, Hain’s labels and advertisements touted Earth’s Best Baby Foods as “pure quality products,” “pure,” “organic,” made with “no genetically engineered ingredients,” “babies perfect first solid food,” “whole grain natural goodness,” “grown without potentially harmful pesticides or herbicides,” and “easily digestible.” Compl. ¶¶ 42; 102-104. But, unbeknownst to Plaintiffs and consumers, Hain’s ingredient testing revealed, amongst other things, that: (i) “6 ingredients contained more than 200 ppb lead;” (ii) “total arsenic levels exceed[ed] 75 ppb and inorganic arsenic levels exceed[ed] 90 ppb;” (iii) “14 ingredients contained more than 100 ppb cadmium;” (iv) “barley flour contained 260 ppb cadmium;” and (v) “102 ingredients contained more than 20 ppb cadmium.” Compl. ¶¶ 72, 75, 77. Additionally, tests conducted by Healthy Babies Bright Futures confirmed perchlorate was present in Hain Baby Foods. *Id.* The Congressional Subcommittee “affirmatively found that Hain’s products contain Toxic Heavy Metals and/or other toxins and that its internal specifications permit dangerously high levels.” ¶¶ 13, 179 (“Plaintiffs and members of the Class sustained damages as a direct and proximate result of Defendant’s breaches insofar as they paid a premium for Defendant’s Baby Foods that they would not have otherwise paid had they known that Defendant’s Baby Foods contained dangerous levels of Toxic Heavy Metals and/or other toxins.”). On its face, the Complaint certainly alleges Plaintiffs “paid more for the product than he or she would have if the defendant did not engage in allegedly deceptive practices.” *Colpitts*, 527 F. Supp. 3d at 576-77.

Further, contrary to Defendant’s argument, “[a] plaintiff need not specify in her pleading the exact amount of price premium that she paid.” *Brown*, 2021 WL 5446007, at *3. *In re Frito-Lay N. Am., Inc. All Nat. Litig.*, is instructive, finding “there is no doubt” plaintiffs sufficiently alleged standing where plaintiffs purchased the products and pled “[t]hey were injured as a result of those purchases because they paid higher prices than they would have

otherwise paid, or not paid at all, for a product that they contend is not, in fact, all natural.” 2013 WL 4647512 at *11. As in *In re Frito-Lay*, Plaintiffs’ Complaint states a plausible theory demonstrating economic injury. Hain marketed its products as “pure,” “pure quality products,” “organic,” made with “no genetically engineered ingredients,” “babies perfect first solid food,” “whole grain natural goodness,” “grown without potentially harmful pesticides or herbicides,” and “easily digestible” and Plaintiffs relied on those misleading misrepresentations when they paid a premium price for Hain’s products that were not, in fact, as Hain marketed them but, instead, contained Dangerous Toxins. Compl. ¶¶ 102-104.⁶

In another example of Defendant’s misapplication of the legal standard, Defendant argues that Plaintiffs must plead alternative products containing guarantees that no Dangerous Toxins exist. That is not true, and such an argument is both legally and procedurally improper. It is legally improper because it reformulates the clear price premium injury standard. Courts have not required Plaintiffs to plead alternative products, particularly in cases demonstrating “classic example[s]” of price premium injury. *Belcastro*, 2017 WL 5991782 at *5 (collecting cases demonstrating cognizable price premium injury). Second, Defendant’s argument relies on facts that contradict those pled in the Complaint. *See Gibson*, 2022 WL 784746, at *2 (“When considering a Rule 12(b)(1) motion, the court must take all uncontroverted facts in the complaint . . . as true, and draw all reasonable inferences in favor of the party asserting jurisdiction.”). While not required to plead alternatives, Plaintiffs do, indeed, allege alternative products, including Nature One, Cerbelly, Once Upon a Farm, and Yumi, which have been tested in

⁶ Under Second Circuit law, misstatements in labels and advertisements must be viewed holistically for the impression they create on consumers, rather than an individualized view of each term. *Mantikas v. Kellogg Co.*, 910 F.3d 633, 636 (2d Cir. 2018) (requiring Courts to “consider the challenged advertisement as a whole”).

“independent laboratory tests” and “regularly test[ed] at *zero* for harmful contaminants” like Dangerous Toxins. Compl. ¶¶ 116-120.

2. Plaintiffs did not receive the benefit of their bargain.

Plaintiffs alternatively establish economic injury pursuant to a benefit of the bargain theory. At its core, benefit of the bargain injury requires a showing of “some concrete and particularized injury in paying for one item and receiving another, even if you ultimately receive the benefit of your bargain from a purely objective economic standpoint.” *Borenkoff v. Buffalo Wild Wings, Inc.*, 2018 WL 502680, at *4 (S.D.N.Y. Jan. 19, 2018). In *Borenkoff*, the plaintiff, a vegetarian, only alleged “that she wouldn’t have purchased defendants’ food items if she had known they were fried using beef tallow.” While the Court acknowledged that “courts have raised doubts as to whether that type of alleged economic injury is cognizable,” the Court reaffirmed the Second Circuit’s “low threshold” for establishing injury-in-fact on a motion to dismiss. *Id.* Here, Plaintiffs go beyond *Borenkoff* by pleading far more to support a benefit of the bargain injury. Compl. ¶ 180. Indeed, the Complaint plausibly alleges that the presence of the Dangerous Toxins in Hain’s Baby Foods has “propensity to cause adverse health implications” and “were unsafe and unsuitable for babies.” *See* Compl. ¶¶ 157, 174, 205, 208, 212, 223, 228.⁷

3. Plaintiffs establish economic injury; physical injury is not necessary.

As Defendant Hain is aware, this is a false advertising and deceptive practices case, and economic injury is sufficient to establish Article III standing. When the cases were consolidated before this Court, Hain specifically requested that physical injury be excluded and that the consolidated cases focus solely on economic injury. *See* ECF No. 28 (“Hain Celestial nonetheless

⁷ Plaintiffs note that here, the Court is not required to make any determinations as to the safety of the levels of Dangerous Toxins in Hain’s products because Hain made its own safety determinations, presumably on the basis of science and testing, to determine the levels of Dangerous Toxins that are “acceptable” or safe to be fed to infants. Compl. ¶¶ 91-93.

objects to Plaintiffs’ request for consolidation to the extent it encompasses lawsuits asserting product liability or personal injury claims”); ECF No. 47 (“It is hereby ordered that . . . any and all personal injury and product liability claims for non-economic damages . . . shall not be asserted in the Consolidated Action.”). Defendant now files a brief before this Court accusing Plaintiffs of not demonstrating some physical injury to prove that the toxins, and therefore the baby foods, were dangerous. Hain cannot have it both ways. As indicated above, Plaintiffs sufficiently allege Article III standing due to the economic injury suffered.

Courts have rejected similar arguments where, as here, plaintiffs “do not rely on a risk of future injury as grounds for economic loss; instead they argue that they overpaid (or purchased the product at all) because of [defendant]’s past misrepresentations. *In re Evenflo Co., Inc., Mktg., Sales Pracs. & Prod. Liab. Litig.*, 54 F.4th 28, 36-37 (1st Cir. 2022) (finding this holding “consistent with precedent from other circuits,” in part, because “[m]ultiple Second Circuit decisions have determined that plaintiffs had standing based on overpayment due to a defendant’s false or misleading statements”).

Defendant continues to argue that physical injury is necessary while ignoring Plaintiffs’ clear allegations of economic injury and cherry-picking allegations from throughout the Complaint to fabricate its own version of Plaintiffs’ Article III standing allegations. MTD at 13-14. In making this flawed argument, Defendant relies on *Kimca I*, *Herrington*, and *Plum/Campbell*. *Kimca I*, 2022 WL 1213488, at *5; *Herrington v. J&J Consumer Cos.*, 2010 WL 3448531 (N.D. Cal. Sept. 1, 2010); *In re Plum Baby Food Litig. (Plum/Campbell)*, 2022 WL 16552786 (D.N.J. Oct. 31, 2022). These out-of-circuit cases do not apply to the well-pled economic injury allegations in this action.

Kimca I is not precedential and inapposite because, unlike Plaintiffs in *Kimca I*, Plaintiffs here establish economic injury. There, the Court determined that Plaintiffs failed to “adequately alleg[e] that Sprout’s alleged misrepresentations and omissions caused them to pay an unfair premium price.” *Kimca I*, 2022 WL 1213488, at *8. In contrast, Plaintiffs in this action explicitly

allege that “Defendant’s advertising and products’ packaging and labeling induced Plaintiffs and members of the Class to buy Defendant’s products and to pay a premium price for them.” Compl. ¶ 215. This allegation is bolstered by Hain’s misleading statements which induced Plaintiffs to purchase the premium products based on the fact they were advertised as “pure,” “organic,” “natural,” and “babies’ perfect first solid food.” Compl. ¶¶ 102-104. Moreover, Hain touted these products as “Earth’s Best” or at least better than competing, lesser priced baby food products. Compl. ¶¶ 116-120. Viewed holistically, these allegations provide far stronger support for a price premium injury than those in *Kimca I*. For these reasons, this Court need not reach the increased risk of future harm inquiry as the Court in *Kimca I* did.

Even under an increased risk of future harm analysis, Plaintiffs here still need not demonstrate actual physical injury. In *Kimca I*, the Court found Plaintiffs failed to allege a necessary link between the presence of heavy metals in the products at issue and the fact that heavy metals are unsafe. Specifically, the Court found Plaintiffs failed to allege that the levels of heavy metals in the baby products *at issue* were unsafe. Therefore, it was not enough for Plaintiffs to simply show that the baby foods they purchased contained heavy metals and that heavy metals are generally dangerous catalysts for increased risk of future harm. *Herrington* similarly holds that Plaintiffs lacked the key link establishing that the products actually contained dangerous levels of the “probable carcinogens” at issue in a way that substantially increased the risk of future harm. *Herrington*, 2010 WL 3448531, at *3.

Contrary to these cases, Plaintiffs have established this link. Unlike *Kimca I* and *Herrington*, the Complaint provides three key metrics to make this showing: (i) Defendant Hain’s own internal standards for “acceptable levels” of Dangerous Toxins; (ii) Congressional Report’s test results demonstrating that Defendant Hain exceeded its own internal standards; and (iii) an outline of FDA, EPA, and WHO guidelines for levels of Dangerous Toxins in other products regularly consumed by infants (*e.g.*, drinking water) as a point of reference for the danger of toxins at these levels. *See*

Compl. ¶¶ 45-70. The levels of Dangerous Toxins in Earth’s Best Baby Foods, demonstrated by Congressional testing, exceeded Hain’s internal standards which Hain deemed “acceptable;” Hain presumably set these guidelines based on scientific testing and safety measurements. Moreover, the levels of Dangerous Toxins actually present in Hain’s ingredients exceeded similar guidelines for products regularly consumed by infants. Compl. ¶¶ 46; 52; 55; 58-60; 71; 74; Under a Rule 8 pleading standard, it is certainly plausible that the high levels of Dangerous Toxins in Hain’s products were not just presumably unsafe, but actually unsafe based on these metrics.⁸ Thus, exposure to these high levels of Dangerous Toxins placed infants at a substantially greater risk of harm, including “serious[] harm [to] children’s development and health, specifically, [of] the brain and nervous system.” Compl. ¶ 48 (“even low-level chronic exposure can be hazardous over time”). At the very least, the levels of Dangerous Toxins present in Earth’s Best Baby Food ingredients were harmful by Hain’s own definition – established by Hain’s guidelines for “acceptable” levels of Dangerous Toxins which it exceeded. Compl. ¶¶ 91-93

Defendant also relies on the *Plum/Campbell* case which is distinguishable. There, the Court assessed physical injury-in-fact after finding that plaintiffs failed to allege economic injury in fact. This failure stemmed from plaintiffs’ “threadbare allegations” that failed to (i) show “Defendant actually advertised the product as superior to others,” and (ii) allege alternative comparable products. *Plum/Campbell*, 2022 WL 16552786 at *8. In contrast, Plaintiffs here demonstrate that Defendant unquestionably advertised its product as superior to other baby foods. Standing alone, Hain’s brand name “Earth’s Best” demonstrates this point. This name, paired with a variety of label representations, such as “organic” and “pure” further promote the superiority of Hain’s products. Additionally, Plaintiffs explicitly plead safer alternatives including, Nature One, Cerbelly, Once Upon a Farm, and Yumi. Compl. ¶¶ 116-120.

⁸ Because reasonable consumers consider these products unsafe due to the levels of Dangerous Toxins, the omission of these levels would be material to consumers. See III. B.

4. Plaintiffs have standing to seek injunctive relief.

Defendant's final jurisdictional argument seeks to dismiss Plaintiffs' claims for injunctive relief based on their purported failure to demonstrate any risk of future harm. But this showing is not required. Courts in the Second Circuit routinely find that "a Plaintiff in a consumer protection suit has standing to seek injunctive relief regardless of any promises to purchase the products in questions in the future." *Petrosino v. Stearn's Prods., Inc.*, 2018 WL 1614349, at *5 (S.D.N.Y. Mar. 30, 2018); *see also Ackerman v. Coca-Cola Co.*, 2013 WL 7044866, at *15, n.23 (E.D.N.Y. July 18, 2013); *Belfiore v. P&G Co.*, 311 F.R.D. 29, 67 (E.D.N.Y. 2015). At most, these cases have merely required that Plaintiffs express that they "would purchase the Products again if the ingredients were changed" so they comport with the label's representations. *See Petrosino*, 2018 WL 1614349, at *4. Here, Plaintiffs require that the levels of Dangerous Toxins be disclosed before purchasing again in the future – a request less burdensome than the ingredient changes requested in other cases. Compl. ¶ 43.

Even if Plaintiffs are required to demonstrate a likelihood of being "harmed again in the future in a similar way" (*Nicosia*, 834 F.3d at 239), as Defendant alleges, Plaintiffs meet this heightened standard. Plaintiff Carolyn Leary has not stopped purchasing Earth's Best Products and continues to face a risk of future harm. Compl. ¶¶ 24, 33.

For all the reasons stated above, Plaintiffs sufficiently demonstrate standing to seek injunctive relief. The law requires that Plaintiffs "demonstrate standing for each claim and form of relief sought." *Petrosino*, 2018 WL 1614349, at *4. Plaintiffs do just that.

B. Plaintiffs state a plausible claim for relief.

Plaintiffs assert sixteen state law consumer protection act claims. The core issue of each of these claims is whether a reasonable plaintiff was misled by the Defendant's false advertising or mislabeling. Plaintiffs establish this deception in their well-pled complaint. Hain, however,

attempts to dispose of Plaintiffs’ well-pled materiality allegations with four (4) improper fact-based arguments:⁹ (i) the Complaint contains no plausible allegations that it misled consumers about the presence of Dangerous Toxins because Dangerous Toxins naturally occur in the environment, (ii) naturally occurring Dangerous Toxins do not render Hain’s labels on its Earth’s Best Baby Foods misleading, (iii) Hain’s labeling misrepresentations are puffery, and (iv) the “organic” label is not actionable as it is preempted. MTD at 22-29. These arguments ignore Plaintiffs’ allegations that they were materially misled to believe Earth’s Best Baby Foods did not contain Dangerous Toxins.

1. Whether a reasonable consumer is misled is a question of fact.

Consumer protection and deceptive practices claims are subject to a reasonable consumer standard. *See Orlander v. Staples, Inc.*, 802 F.3d 289, 300 (2d Cir. 2015) (assessing the misrepresentation under an “objective” standard determining whether the label is “likely to mislead a reasonable consumer acting reasonably under the circumstances”). Accordingly, this analysis requires a factual determination that is premature on a motion to dismiss. *See Cooper v. Anheuser-Busch, LLC*, 553 F. Supp. 3d 83, 96 (S.D.N.Y. 2021) (“this inquiry is generally a question of fact not suited for resolution at the motion to dismiss stage”) (collecting cases). In direct contravention of this standard, Defendant seeks a determination as a matter of law, affirmatively finding no reasonable consumer could be misled about the presence of Dangerous Toxins in Hain’s products based on its labels and advertisements. However, a decision as a

⁹ Defendant Hain solely challenges the materiality element of Plaintiffs’ sixteen consumer protection act claims and common law claims for breaches of express and implied warranty, negligent misrepresentation, unjust enrichment, and fraudulent concealment. MTD at 23. Because Plaintiffs establish materiality, these claims may survive Defendant’s motion to dismiss. Further, by failing to raise arguments to each element of Plaintiffs’ claims, Defendant waives the arguments. *Schluter Sys., LP v. Sanven Corp.*, 2022 WL 17617807, at *2 (N.D.N.Y. Dec. 13, 2022) (“a party waives a number defenses, including lack of personal jurisdiction, by: failing to either: (i) make a motion under this rule; or (ii) include it in a responsive pleading or in an amendment allowed by Rule 15(a)(1) as a matter of course.”).

matter of law is the “exception[] to the norm.” *Id.* It is rare for Courts to deviate from this standard given that this “is normally a question of fact that cannot be resolved on a motion to dismiss.” *See id.* citing *Segedie v. Hain Celestial Grp., Inc.*, 2015 WL 2168374, at *12 (S.D.N.Y. May 7, 2015).

2. Reasonable consumers are misled by Hain’s advertisements.

Defendant attempts to combat Plaintiffs’ plausible allegations with its own facts. Hain divides the misstatements and argues that because each statement may be true, it cannot be materially misleading. MTD at 25-27.¹⁰ However, this argument is improper under Second Circuit standards which requires the question whether the advertising, packaging, and labeling is misleading to be analyzed as a “whole” and in “context.” *Mantikas v. Kellogg Co.*, 910 F.3d 633, 636 (2d Cir. 2018) (requiring Courts to “consider the challenged advertisement as a whole”). Further, Plaintiffs are not required to demonstrate that a given misstatement is actually false. Instead, Plaintiffs must merely demonstrate that the misstatements and omissions, taken as a whole, have a tendency to create a particular impression on a reasonable consumer. *Leonard v. Abbott Labs., Inc.*, 2012 WL 764199, at *20 (E.D.N.Y. Mar. 5, 2012). Plaintiffs plead several plausible scenarios under which reasonable consumers could be (and were) deceived. Moreover, whether consumers were misled is a question of fact inappropriate for a motion to dismiss.

“The allegations in this case do not present the type of *patently implausible* claim that warrants dismissal as a matter of law.” *Stoltz v. Fage Dairy Processing Indus., S.A.*, 2015 WL 5579872, at * 20 (E.D.N.Y. Sept. 22, 2015). “To the contrary, Plaintiffs have cogently explained how reasonable consumers might be misled into thinking that the Products were” free of Dangerous Toxins. *Cooper*, 553 F. Supp. 3d at 96. For example, a reasonable interpretation of

¹⁰ Defendant cannot rely on FDA materials not included in the Complaint for the sake of creating factual arguments. *Cooper*, 553 F. Supp. 3d at 96 (holding factual determination is inappropriate at this stage).

“pure, quality products” and “made with superior ingredients” could mislead a consumer to believe their infant baby food products did not contain high levels of Dangerous Toxins. Compl. ¶¶ 4; 104. These misleading statements paired with “Grown without Potentially Harmful Pesticides or Herbicides,” lead reasonable consumers to believe that Earth’s Best Baby Foods were free of Dangerous Toxins, especially in excessive quantities. *See* Compl. ¶ 103. Also, consumers may reasonably perceive labels touting “natural goodness” and “gentle” qualities to mean safe, not dangerous, or free of Dangerous Toxins. Courts routinely find similar misstatements sufficient on a motion to dismiss. *See Buonasera v. Honest Co., Inc.*, 208 F. Supp. 3d 555, 559, 566 (S.D.N.Y. 2016) (finding allegations that defendant’s labels contained “natural,” “all natural,” “naturally derived,” “plant-based,” and containing “no harsh chemicals ever!”, when the products contained “toxic ingredients,” materially misleading); *Pelman ex rel. Pelman v. McDonald’s Corp.*, 396 F.3d 508 (2d Cir. 2005) (reversing dismissal where McDonald’s overall message conveyed misleading and/or false information about its products). Additionally, the challenged statements need not directly relate to Dangerous Toxins, but instead, must support a reasonable interpretation of the overall message in context. *See In re Frito-Lay N. Am., Inc. All Nat. Litig.*, 2013 WL 4647512, at *16 (E.D.N.Y. Aug. 29, 2013) (“a reasonable consumer viewing the [] labels could reach a variety of conclusions about their potential for containing genetically modified ingredients”).

Defendant’s remaining arguments consist of factual assertions that contradict Plaintiffs’ Complaint and cannot be considered on a motion to dismiss. *Anheuser-Busch, LLC*, 553 F. Supp. 3d at 96. First, Defendant asserts that the Dangerous Toxins are naturally occurring in the environment. For this reason, Hain asserts that reasonable consumers would expect heavy metals to be present in foods and their presence, therefore, would not be material. This improper

factual argument ignores Plaintiffs’ plausible allegations that Earth’s Best Baby Food contained Dangerous Toxins *at higher-than normal-levels*.¹¹ Plaintiffs have no way of knowing the true dangers of Earth’s Best Products because Hain failed to test its finished goods. Defendant’s cases in support of this argument are inapplicable. Defendant cites to *Parks* which dealt with “negligible amounts of glyphosate” and lacked allegations demonstrating any harm that could be caused by glyphosate to dogs. *Parks v. Ainsworth Pet Nutrition, LLC*, 377 F. Supp. 3d 241, 248 (S.D.N.Y. 2019). The excessive levels of Dangerous Toxins at issue here are far more material. *Parks* is further distinguishable because Plaintiffs explicitly allege that these Dangerous Toxins cause “serious[] harm [to] children’s development and health, specifically the brain and nervous system.” Compl. ¶ 48 (“even low-level chronic exposure can be hazardous over time”). For the same reason, *Herrington* does not apply. *Herrington*, 2010 WL 3448531, at *1.

Finally, and contrary to Defendant’s assertion, Plaintiffs’ claims concerning the “organic” labeling are not preempted. *See Holve v. McCormick & Co., Inc.*, 334 F. Supp. 3d 535, 555 (W.D.N.Y. 2018) (rejecting Defendant’s preemption argument because Plaintiffs’ claims do not concern labeling requirements and only turn on whether the label was deceptive). Plaintiffs do not challenge the certification of Earth’s Best Products as organic. Rather, Plaintiffs allege that Defendant’s advertising and labeling touts its Products as nutritious and pure and, when taken as a whole, would lead a reasonable consumer to believe that the products did not include Dangerous Toxins.

¹¹ In fact, the levels of Dangerous Toxins in Earth’s Best Baby Food ingredients exceeded Hain’s own internal standards for what Hain defined as “acceptable” for manufacturing and sale to infants. Compl. ¶¶ 91-93. Defendant’s cited out-of-circuit case, *Song v. Champion PetFoods, Inc.*, is inapposite because Plaintiffs need not show harm to render statements misleading even if Dangerous Toxins are naturally occurring. MTD at 26; 27 F, 4th 1339 (8th Cir. 2022). In the Second Circuit, “[t]he fact that Plaintiffs do not allege that the [] food contained unsafe levels of heavy metals . . . does not, at least at this stage, undermine the claim that the advertising was deceptive.” *Colangelo v. Champion Petfoods USA, Inc.*, 2020 WL 777462, at *5 (N.D.N.Y. Feb. 18, 2020).

3. Defendant Hain's misrepresentations are actionable, not puffery.

The statements Hain used to describe the characteristics of its products are misleading and actionable. Defendant Hain asserts that the misrepresentations “pure,” “nurturing baby the purest way,” and “made with superior ingredients” are non-actionable puffery, but that is inconsistent with the law in this district. Courts in this district have developed a framework for assessing whether a misrepresentation constitutes puffery. This involves examining a misstatement for “(i) vagueness; (ii) subjectivity; and (iii) inability to influence the buyers’ expectations.” *Avola v. Louisiana-Pac. Corp.*, 991 F. Supp. 2d 381, 392 (E.D.N.Y. 2013). If a misstatement is determined to be vague, subjective, and non-influential, then it is non-actionable puffery.

Puffery, however, is “distinguish[ed] from misdescriptions or false representations of specific characteristics of a product.” *Avola*, 991 F. Supp. 2d at 392. Claiming a product is “pure” or can nurture a baby in a pure manner is neither vague nor subjective. Thus, where Defendant makes an “affirmative claim about a product’s qualities” that claim is actionable. *See Mogull v. Pete & Gerry’s Organics, LLC*, 588 F. Supp. 3d 448, 454 (S.D.N.Y. 2022).

C. The primary jurisdiction doctrine does not apply to stay or dismiss this case.

“The federal courts have a virtually unflagging obligation . . . to exercise the jurisdiction given [to] them.” *Palmer v. Amazon.com, Inc.*, 51 F.4th 491, 504 (2d Cir. 2022). Thus, this (primary jurisdiction) doctrine only applies in a “relatively narrow” set of circumstances (*Goya Foods, Inc. v. Tropicana Prods., Inc.*, 846 F.2d 848, 851 (2d Cir. 1988)) and does not apply where Courts are asked to determine whether consumers were misled by false and deceptive advertisements and labels that omit the true contents of a product. In fact, Courts routinely reject primary jurisdiction arguments in false advertising and mislabeling class actions. *See In re Frito-Lay N. Am., Inc. All Nat. Litig.*, 2013 WL 4647512, at *8; *Janney v. Mills*, 2013 WL

1962360, at *3–7 (N.D. Cal. May 10, 2013); *Krzykwa v. Campbell Soup Co.*, 2013 WL 2319330, at *4 (S.D. Fla. May 28, 2013); *Briseno v. ConAgra Foods, Inc.*, 2011 WL 7939790 (C.D. Cal. June 28, 2011).

Despite this well-settled law, Hain argues that this action should be dismissed or stayed pursuant to the primary jurisdiction doctrine. However, as this Court already expressed an inclination to reject Defendant’s argument and find that the factors weigh *against* a dismissal or stay during the September 21, 2022 hearing. ECF No. 177. In making this and similar assessments, Courts consider four factors: (i) if the issue “is within the conventional experience of judges” or if “it involves technical or policy considerations within the [FDA’s] particular field of expertise;” (ii) “whether the question at issue is particularly within the [FDA’s] discretion;” (iii) “whether there [is] a substantial danger of inconsistent rulings;” and (iv) “whether a prior application to the agency has been made.” *Goldemberg v. J&J Consumer Cos., Inc.*, 8 F. Supp. 3d 467, 476 (S.D.N.Y. 2014). This Court’s September 21, 2022 inclination was correct and Defendant has not raised any new arguments that would warrant a dismissal or stay.

1. The Court is well-equipped to address the issues in this case.

The first factor weighs against a dismissal or stay because determining whether a label could mislead consumers is well within the conventional experience of judges. “The question whether defendants have violated FDA regulations and marketed a product that could mislead a reasonable consumer is one courts are well-equipped to handle.” *Ackerman*, 2010 WL 2925955, at *14 (E.D.N.Y. July 21, 2010). “Generally, the judiciary is well-suited to determine a consumer’s reasonable expectations about labeling.” *Belfiore*, 311 F.R.D. at 75; *see also In re Frito–Lay N. Am., Inc. All Nat. Litig.*, 2013 WL 4647512 at *8 (“There is no doubt the issues are well “within the conventional experience of judges.”); *Lockwood v. ConAgra Foods, Inc.*, 597 F. Supp. 2d 1028, 1035 (N.D. Cal. 2009) (“[E]very day courts decide whether conduct is

misleading.”). This case is no different. As the law demonstrates, this Court is well-suited to determine whether reasonable consumers were misled by the contents of Defendant Hain’s labels and advertisements.

Defendant’s cited cases do not alter this well-settled law. MTD at 8-9. Plaintiffs’ claims do not require novel scientific determinations about whether compounds like genetically engineered foods, chemically synthesized ingredients, or processed ingredients are in fact natural or healthy. In *Colella v. Atkins Nutritionals, Inc.*, the FDA had already “promulgated rules regarding the precise types of nutrient content claims and disclosure requirements” so, the Court found the first factor weighed in favor of applying the primary jurisdiction doctrine. 348 F. Supp. 3d 120, 140 (E.D.N.Y. 2018). This is distinguishable because here the FDA has issued no such rules and disclosure requirements to govern heavy metals in baby foods. Similarly, *Forsher v. J.M. Smucker Co.*, is inapplicable because the Court only deferred to the FDA to decide a novel issue after “several federal courts had previously requested administrative determinations from the FDA.” 2016 WL 5678567 (E.D.N.Y. Sept. 30, 2016) (recognizing FDA determination was necessary to address the novel issue of whether genetically engineered food products were “natural”).

In another example of Defendant’s misapplication of the legal standard, Defendant Hain argues that the issue in this case is “complicated” and requires the Court to make a final determination as to the “appropriate thresholds for heavy metals in food products.” MTD at 8. This is false and misleading statement mischaracterizes the core issue of this case – a false advertising case founded upon reasonable consumers’ interpretation of labels and advertisements. See Section III. B. Indeed, Hain’s own Motion spends eight pages raising arguments as to the true issue of *whether its labels and advertisements are misleading*. MTD at

22-30. For this reason, *Kimca II* is distinguishable. *Kimca v. Sprout Foods, Inc.*, 2022 WL 3586095 at *1–3 (N.J. Super. Ct. Law Div. Aug. 5, 2022) (Applying primary jurisdiction doctrine because the Court found a determination of “what levels of heavy metals in baby foods are safe and acceptable” was required). This Court need not wait for the FDA to determine action levels for heavy metals because Defendant Hain has already made a determination as to the acceptable levels of Dangerous Toxins. Compl. ¶¶ 91-93. Defendant Hain’s own internal standards for acceptable levels of Dangerous Toxins, Hain’s ingredient test results, and the Congressional Subcommittee’s test results will suffice to inform the Court of the levels of Dangerous Toxins in Earth’s Best Baby Foods that exceeded acceptable levels. The remaining inquiry will rest on reasonable consumer’s impressions about the labels and advertisements in light of these metrics. *Gerber* is distinguishable for the same reasons. 2022 WL 10197651, at *13. Moreover, unlike *Gerber*, this is not a case about “harmful” levels of Dangerous Toxins in Hain’s products. *See* Section III. A (3).¹²

The FDA’s potential consideration of proposed “action levels” for baby foods has no bearing on Hain’s misleading advertising of Earth’s Best Baby Food in particular. *See Reed v. 1-800-Flowers.com, Inc.*, 327 F. Supp. 3d 539, 547 (E.D.N.Y. 2018) (finding that “[w]hile Congress may have tasked the [agency] with providing guidance and technical expertise to develop standards . . . it did not charge the [agency] with determining whether a defendant’s actions, or lack thereof, violate” other laws); *In re Methyl Tertiary Butyl Ether (“MTBE”) Prod. Liab. Litig.*, 175 F. Supp. 2d 593, 618 (S.D.N.Y. 2001) (finding although “various” agencies

¹² As discussed at length in Section III. A (3), this case has no bearing on public health risks or physical injury. Therefore, the out-of-circuit *Tran* and *Backus* cases have no bearing here. *Tran v. Sioux Honey Ass’n Coop.*, 2017 WL 5587276, at *3 (C.D. Cal. Oct. 11, 2017); *Backus v. Gen. Mills, Inc.*, 122 F. Supp. 3d 909, 934 (N.D. Cal. 2015).

were investigating “the overall problem” for the purpose of “possible rulemaking” that “none of these agencies are addressing the specific issues raised by plaintiffs’ common law claims”).

2. The second factor alone does not warrant a stay or dismissal.

Contrary to Defendant Hain’s assertions, the question at issue in this case is not within the discretion of the FDA. This case does not concern whether Earth’s Best Baby Foods are “safe,” “sanitary,” or “properly labeled,” according to FDA regulation so 21 U.S.C. § 393(b)(2)(A) does not usurp the Court’s authority here. Even if the FDA has jurisdiction over some issues of food labeling, this Court need not apply the primary jurisdiction doctrine because the remaining three factors weigh heavily against the imposition of a stay or dismissal. *See Greene v. Gerber Prod. Co.*, 262 F. Supp. 3d 38, 53 (E.D.N.Y. 2017) (finding it is well-settled that the second factor alone does not warrant a stay or dismissal under the primary jurisdiction doctrine).

3. There is no risk of inconsistent rulings.

The third factor does not warrant a dismissal or stay because there is no “substantial danger of inconsistent rulings.” *See Goldemberg, Inc.*, 8 F. Supp. 3d at 476. The determinations about advertising and labeling in this case will not usurp the FDA’s authority to interpret or authorize safe levels of heavy metals in baby food. Specifically, Plaintiffs are not seeking a determination as to the safe level of Dangerous Toxins from this Court. Instead, Plaintiffs merely request relief due to the harm they suffered by purchasing Earth’s Best Baby Food products for prices higher than they would have paid had they known the truth about the presence of high levels of Dangerous Toxins in these products. Even if the FDA promulgates “action levels” for heavy metals in baby foods during the pendency of this action, “it [is] unlikely that such a prospective ruling would be inconsistent for the purposes of primary jurisdiction analysis” because any rulemaking will be “presumptively prospective.” *In re DBSD*

N. Am., Inc., 427 B.R. 245, 253 (S.D.N.Y. 2010). “Moreover, the FDA is unlikely to respond in a timely manner to any referral from this Court.” *In re Frito-Lay N. Am., Inc. All Nat. Litig.*, 2013 WL 4647512, at *9; *Ackerman*, 2010 WL 2925955, at *14.

It is critical to note that the risk of differing decisions between this jurisdiction and others is **not relevant** to this factor and should not be considered. *Elkind v. Revlon Consumer Prod. Corp.*, 2015 WL 2344134, at *10 (E.D.N.Y. May 14, 2015) (finding “the Court is less concerned about the danger of” inconsistent rulings amongst other cases and more concerned with the danger of inconsistencies with the FDA) (holding this factor weighed against application of primary jurisdiction doctrine). This factor pertains to this Court’s actions weighed against the FDA alone, not other courts. *See GOJO Indus., Inc. v. Innovative Biodefense, Inc.*, 407 F. Supp. 3d 356 (S.D.N.Y. 2019). Thus, the three cases on which Defendant bases its brief – *Kimca I*, *Gerber*, and *Plum/Campbell* – need not be considered in this analysis.¹³

4. The parties have not made prior applications to the FDA.

Finally, neither party has made an application to the FDA and, contrary to Hain’s position, the mere FDA announcement of a committee or plan to eventually, potentially set “action levels” for Dangerous Toxins in baby foods is insufficient to satisfy this factor. *Reid v. GMC Skin Care USA Inc.*, 2016 WL 403497, at *12 (N.D.N.Y. Jan. 15, 2016) (“if prior application to the agency is absent, this factor may weigh against referral of the matter to the agency on the basis of primary jurisdiction”); *see also Goldemberg*, 8 F. Supp. 3d at 477 (finding fourth factor weighed against dismissal because neither party made an application to the FDA); *Elkind*, 2015 WL 2344134, at *10 (same). The FDA’s “Closer to Zero” plan has no bearing on this false advertising and consumer protection action. The FDA developed this plan for the

¹³ Notably, there is only one action pending against Defendant Hain, further weighing against the application of a stay or dismissal.

purpose of implementing changes to the way food for children and babies will be manufactured prospectively. These efforts, however, will do nothing to provide the retroactive relief sought by Plaintiffs for their prior purchases. Thus, any action the FDA may or may not take as part of this plan will have no bearing on determining whether Hain deceived consumers in marketing and labeling its Earth's Best Products for prior years.

IV. CONCLUSION

For the reasons stated herein, Plaintiffs respectfully request that Defendant's Motion to Dismiss the Complaint be denied in its entirety.

Date: December 22, 2022

Respectfully submitted,

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